K012116

SEP 1 2 2001

Special 510(k) Summary

Contact Person: Dr. Bruce L. Gibbins, Chairman & CTO

Date of preparation: July 3, 2001

Device Name (proprietary): AcryDerm Silver Antimicrobial Perforated Dressing

Common Name: Moist antimicrobial wound dressing

Classification Name: Hydrophilic Wound Dressing

Classification: Unclassified

Legally marketed device(s) for substantial equivalence comparison:

AcryDerm Silver Antimicrobial Strands (AcryMed, Inc., OR)

Description of Device: AcryDerm Silver Antimicrobial Perforated Dressing is a line extension of the previously cleared product, AcryDerm Silver Antimicrobial Strands. The new product is made from the same intermediate base matrix material, has the same composition and is made from substantially an equivalent manufacturing process as the predicate. The new product is an absorbent, perforated hydrophilic polyacrylate perforated sheet wound dressing that contains antimicrobial silver that inhibits the growth of microbial contaminants in contact with the dressing. AcryDerm Silver Antimicrobial Perforated Dressing will be supplied sterile packaged in single use heat sealed medical grade poly-laminate pouches. The single use primaries will be packed, with a product insert, into dispenser boxes for distribution. Biocompatibility has been assessed according to Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

Intended Use of the Device: AcryDerm Silver Antimicrobial Perforated Dressing is an effective barrier to bacterial penetration. The barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

Technological Characteristics: AcryDerm Silver Antimicrobial Perforated Dressing is a perforated sheet dressing that controls wound moisture levels through dual function of donation and absorption. Antimicrobial action is conferred by its content of stabilized antimicrobial silver. The product carries the general classification name, "Hydrophilic wound dressing". The composition of AcryDerm Silver Antimicrobial Perforated Dressing is identical to the predicate device, AcryDerm Silver Antimicrobial Strands. AcryDerm Silver Antimicrobial Perforated Dressing contains silver that may control microbial contamination of the dressing.

Manufacturing: AcryDerm Silver Antimicrobial Perforated Dressing will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2001

Bruce Gibbons, Ph.D.
Chairman and Chief Technical Officer
AcryMed, Inc.
12232 SW Garden Place
Portland, Oregon 97223

Re: K012116
Trade/Device Name: AcryDerm Silver Antimicrobial Perforated Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: August 7, 2001
Received: August 13, 2001

Dear Dr. Gibbons:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Walter, MD for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012116

510(k) NUMBER (IF KNOWN): _____

DEVICE NAME: **AcryDerm Silver Antimicrobial Perforated Dressing**

INDICATIONS FOR USE:

AcryDerm Silver Antimicrobial Perforated Dressing is an effective barrier to bacterial penetration. The antimicrobial barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ___ OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012116